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Medefil's response to FDA comments on 510(k) # K020999

MEDEFIL, INC.

510(k) Summary

Medefil's Normal Saline Flush Syringe

May 9, 2002

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

1.	Reason for 510(k):	Introduction of a modified product
2.	Name of Device:	
	Classification Name	Catheter Intravascular, Small Volume
	Common Name	0.9% Sodium Chloride Injection, USP.
	Proprietary Name	Medefil's Normal Saline I. V. Flush Syringe
3.	Classification:	
	Name/Class	21 CFR 880.5200 Class II
	Panel	General Hospital
	Product Code	NGT
4.	Establishment Registration Number:	1423982
5.	Submitter's Name and Address:	Medefil, Inc. 492 Lunt Avenue Schaumburg, Illinois 60193
6.	Repackaging and sterilization facilities:	Medefil, Inc. 250 Windy Point Drive Glendale Heights, Illinois 60139
7.	Performance Standards:	

No performance standard(s) applicable to this device has been promulgated under Section 514 of the Food, Drug, and Cosmetic Act.

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8. Device Description and Indicated Use:

The Normal Saline Flush Syringe (the DEVICE) is a single dose, disposable, sterile, plastic pre-filled syringe. The DEVICE consists of a hypodermic syringe with a hypodermic barrel, stopper plunger, plunger rod, tip cap and 0.9% Sodium Chloride Injection, USP. Two different sizes (6 mL, 12 mL) of hypodermic syringes will be utilized in manufacturing. The DEVICE will be marketed in the following dosage forms:

1 mL fill in 6 mL Syringe LL
2 mL fill in 6 mL Syringe LL
2.5 mL fill in 6 mL Syringe LL
3 mL fill in 6 mL Syringe LL
3 mL fill in 12 mL Syringe LL
5 mL fill in 6 mL Syringe LL
5 mL fill in 12 mL Syringe LL
10 mL fill in 12 mL Syringe LL

The barrel of the syringe is the reservoir for the product. It shall be overfilled during repackaging as per Pharmacopoeial Forum, Volume 26, Number 2: page 471. Plunger and plunger rod are the two moving parts of the DEVICE. The solution is delivered by pressing down on the plunger rod, resulting in the expulsion of the fluid from the luer tip.

The DEVICE will be filled using aseptic technique utilizing pre-sterilized components in a Class 100 environment. The sterile components of the DEVICE (hypodermic syringe, tip cap and 0.9% Sodium Chloride Injection, USP) will be purchased from qualified vendors.

The DEVICE is used to maintain patency of in-dwelling intravenous access devices (IVAD). The solution is delivered by pressing down on the plunger rod, resulting in the expulsion of the fluid from the luer tip.

9. Packaging:

The DEVICE provided is individually packaged in a plastic pouch (dust cover). There are six individually packaged DEVICES in a "strip". Twenty such strips (120 individually packed syringes) or 30 individually packed devices will be packed in a card board box.

The DEVICE shall be pyrogen free per the LAL test method for bacterial endotoxin.

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10. Substantial Equivalence:

The Normal Saline Flush Syringe DEVICE is substantially equivalent to the legally marketed predicate device listed below:

Medefil, Inc.
Normal Saline I. V. Flush Syringe
(K993515)

The Medefil's Normal Saline Flush Syringe Device is similar to the legally marketed predicate device in that:

a) both have the same intended use: to maintain patency of indwelling IVAD
b) both have the same concentration, 0.9% sodium chloride, pre-filled solution.
c) both function under the same principle of operation including independent moving parts like stopper and plunger rods.
d) both nozzle tips are compatible with female luer fitting.
e) both fluid container materials are biocompatible and chemically compatible with 0.9% Sodium Chloride solution.
f) both have a sterile, pyrogen free 0.9% sodium chloride fluid and fluid path.
g) the fluid container material is same for both devices – polypropylene
h) both devices use silicone as a lubricant.
i) the fluid is expelled out of the syringe barrel of both the devices by pressing on the plunger for hypodermic syringe
j) both the devices are filled using aseptic filling process.

The DEVICE is different from the predicate device, without adverse affect to safety or efficacy, in that:

a) the dead space (distance between plunger tip and end of the luer lock nozzle tip, when plunger is fully depressed) of the DEVICE is more than that of Medefil's Normal Saline I. V. Flush Syringe.
b) the DEVICE is available in two different syringe barrel size – 6 mL and 12 mL where as predicate device is also available in 3 mL size.
c) the diameter of the DEVICE syringe barrel is more than that of the predicate device. This is due to the fact that diameter of the barrel is inversely proportional to the amount

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of "**infusion pressure**" generated when the plunger is pushed for expulsion of fluid. The larger diameter of the barrel is advantageous so that damage is not done to the patient veins especially pediatric patients.

d) the DEVICE will be manufactured using **fully automates syringe filling machine** whereas the predicate device is manufactured using semi – automated syringe filling machine. But both the machines work on the same principle. Semi – automated syringe filling process requires lot of involvement of the operators during the filling and sealing process but a fully automated process decreases operator contact and opportunity for product contamination.

END OF SUMMARY

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DEPARTMENT OF HEALTH & HUMAN SERVICES · Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2002

Mr. Pradeep Aggarwal
President
Medefil, Incorporated
492 Lunt Avenue
Schaumburg, Illinois 60193

Re: K020999
Trade/Device Name: Normal Saline IV Flush Syringe
Regulation Number: 880.5200
Regulation Name: Device, Flush, Vascular Access
Regulatory Class: II
Product Code: NGT
Dated: May 28, 2002
Received: May 31, 2002

Dear Mr. Aggarwal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~Pending~~ K020999

Device Name: Normal Saline I. V. Flush Syringe

Indications For Use:

FOR USE TO MAINTAIN PATENCY OF IN-DWELLING INTRAVENOUS ACCESS DEVICES (IVAD)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020999

(Optional Format 3-10-98)